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EXAMINER

HANDY, DWAYNE K

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 12/19/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/924,382

Applicant(s)
Gebrian et al.

Examiner
Dwayne K. Handy

Art Unit
1743



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 8, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Aug 8, 2001 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 20) ☐ Other:

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DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the internal ribs recited in claim 3 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 4, the limitation placed on the flange element of “shaped to seat into a mounting groove within an environmentally controlled chamber so that the rotor canister may be secured within the mounting groove in a vertical position” is unclear. Applicant has placed a limitation on the container that is based on a feature of another, unclaimed device. The Examiner can also envision a wide variety of shapes for a groove that has no description other than having

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the property of being able to secure a canister. Therefore, the Examiner contends the claim is indefinite. Also, the term "the rotor canister" lacks antecedent basis in claim 4.

In claim 6, the phrase describing the shape of the test device eject port which states "sized to allow the lowermost test device....to be pushed out of the canister by a plunger". Again, applicant appears to be attempting to place a limitation on the container that is based on a feature of another, unclaimed device. In this case, the size limitation on the eject port is linked to a test device which is not part of the originally claimed device. Therefore, the Examiner contends the claim is indefinite.

In claim 9, applicant has claimed an "indented sheet of plastic... extending the length of the canister *between* the front wall and the five-section back wall". The Examiner does not believe that the term "between" does not accurately reflect the location. It appears that this sheet or flange runs the entire length of the canister on the outside of the canister and *at the juncture* of the front and back walls. Appropriate correction is required.

Inventorship

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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7. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abe (5,534,224) in view of Croteau et al. (5,700,655). Abe teaches a chemical analysis cartridge which holds film chips that are stacked inside the casing. The cartridge is a box-like casing body with opposing first and second end walls and a first opening in a side wall of the casing body for removing the chips from the cartridge. The cartridge is best shown in Figure 1A and described in columns 8 and 9. The cartridge of Abe does not teach an irregular back and side walls that combine to form a generally hexagon shaped interior for housing circular test devices. Croteau et al. teaches a circular shaped test device for incubating test samples in wells. The device contains wells that are adapted to hold a liquid while the plate is placed in an incubator until the presence or absence of biological material is determined. It would have been obvious to one of ordinary skill in the art to combine the shape of the test device of Croteau with the cartridge of Abe. One would alter the shape of Abe's cartridge to accommodate circular test devices such as the one taught by Croteau.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abe (5,534,224) and Croteau et al. (5,700,655) as applied to claims 1 and 2 above, and further in view of Masterson et al. (5,645,800). Abe and Croteau, as combined in paragraph 7 above, teach every element of claim 3 except for the internal ribs extending along the interior of the walls for securing test devices within the canister. Masterson et al. teach a system for processing specimen kept in microplates. The microplates are housed in stations (14) that hold the specimen trays for

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incubation. The stations are best shown in Figures 9-12 and include support ledges (210, 212) formed on the sidewalls that comprise slots for securing the microplates in the stations. It would have been obvious to combine the ledges from the stations of Masterson with the combined teachings of Abe and Croteau. One would add the ledges to the cartridge to provide support to the devices held in the cartridge.

9. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abe (5,534,224) and Croteau et al. (5,700,655) as applied to claims 1 and 2 above, and further in view of Hendrix et al. (5,391,352). Abe and Croteau, as combined in paragraph 7 above, teach every element of claims 4-6 except for the flanges extending above and below the top and bottom of the container. Hendrix et al. teach a system for analyzing a fluid that utilizes a cuvette that holds multiple samples in pockets formed within the device. The cuvette also contains structures that extend from the cuvette for engaging elements of the processing system. The cuvette is best shown in Figure 2 and described in columns 3 and 4. The cuvette has a front face (20), a rear face (22), a closed lower edge (24), and an upper open edge (26) which is covered by element (46). The cuvette also contains extensions (62, 96) which are engageable by the processing machinery of the system (col. 4, lines 22 and 65). It would have been obvious to one of ordinary skill in the art to combine the extensions from the cuvette of Hendrix with the combined teachings of Abe and Croteau. One would add the extensions in order to assist in the processing machinery engaging the container as taught by Hendrix.

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10. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abe (5,534,224), Croteau et al. (5,700,655), and Hendrix et al. (5,391,352) as applied to claims 4-6 above, and further in view of Roberts et al. (5,871,696). Abe, Croteau et al., and Hendrix et al., as combined in paragraph 9 above, teach every element of claims 7 and 8 except for the pair of protrusions and upwardly extending tab. Roberts teaches a cassette for blood smear slide. The cassette has a holder portion and an alignment surface for orienting a bottom slide in the cassette. The cassette is formed so that a slide extraction device may enter the cassette and remove the slides. The alignment features (elements 94 and 144) are best shown in Figures 2 and 3A and described in column 5, lines 28-50; the tab feature (#141) is described in column 4, line 63 through column 5, line 27. It would have been obvious to one of ordinary skill in the art to combine the alignment and support tab features of Roberts with the combined teachings of Abe, Croteau et al., and Hendrix et al. One would add the alignment features to provide a surface for engaging processing machinery as stated in Roberts. Also the addition of the inclined tab feature would help support elements held in the cartridge and force them towards the back wall.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rainen (6,357,583) discloses a circular shaped assembly for holding biological samples in wells. Schacher (5,496,519) shows a diagnostic processing station which uses


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cuvettes with a flange element for engaging the rotor of the system. Seto (5,731,207), Terashima (5,536,472), and Kanamori et al. (5,209,903), Regan et al. (6,361,745), Gianino (5,736,101), and Titcomb et al. (6,004,512) teach cartridges for holding test elements in an analysis system.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-772-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.


Jill Warden
Supervisory Patent Examiner
Technology Center 1700

dkh

December 9, 2002